

Notice of Allowability	Application No.	Applicant(s)	
	09/591,447	CHATFIELD ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/07/03.
2. ☒ The allowed claim(s) is/are 1,7-9,11-17, ²⁰27, 31-33 and 35-45 (renumbered as 1-27).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).


* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2003 has been entered.

Amendment Entry

B. The amendment filed November 7, 2003 has been entered. Claims 2-6, 10, 18-19, 21-26, 28-30 and 34 have been cancelled. Claims 1, 7, 20 and 31, have been amended. Claims 42-45 have been added. Claims 1, 7-9, 11-17, 20, 27, 31-33, and 35-45 are under consideration in this office action.

C. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

D. Authorization for this examiner's amendment was given in a telephone interview with Patrick O'Connell on February 11 and 12, 2004. The application has been amended as follows:

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Claims 1, 8-9, 13, 14, 32, 33, 37 and 38 have been amended as follows:

1. A composition which invokes an immune response to a pathogenic bacterium comprising an immunogen ically effective amount of a pathogenic bacterium attenuated by a non-reverting, defined mutation in the *surA* gene and a pharmaceutically acceptable carrier or diluent.
8. The composition according to claim 7 wherein the second gene is selected from an *aro* gene, *pur* gene, *htrA* gene, *omp* gene, *galE* gene, *cya* gene, *crp* gene or *phoP* gene.
9. The composition according to claim 8 wherein the *aro* gene is selected from *aroA*, *aroC*, *aroD*, or *aroE*.
13. The composition according to claim 1 wherein the bacterium is selected from the genera *Salmonella*, *Escherichia*, *Vibrio*, *Haemophilus*, *Neisseria*, *Yersinia*, *Bordetella* or *Brucella*.
14. The composition according to claim 13 wherein the bacterium is selected from *Salmonella typhimurium*, *Salmonella typhi*, *Salmonella enteritidis*, *Salmonella choleraesuis*, *Escherichia coli*, *Haemophilus influenzae*, *Neisseria gonorrhoeae*, *Yersinia enterocolitica*, *Bordetella pertussis* or *Brucella abortus*.

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20. A method of invoking an immune response in a host to a pathogenic bacterium, which method comprises administering to the host an immunogenically effective amount of a pathogenic bacterium attenuated by a non-reverting, defined mutation in the *surA* gene.

32. The method according to claim 31 wherein the second gene is selected from an *aro* gene, *pur* gene, *htrA* gene, *omp* gene, *galE* gene, *cya* gene, *crp* gene or *phoP* gene.

33. The method according to claim 32 wherein the *aro* gene is selected from *aroA*, *aroC*, *aroD*, or *aroE*.

37. The method according to claim 20 wherein the bacterium is selected from the genera *Salmonella*, *Escherichia*, *Vibrio*, *Haemophilus*, *Neisseria*, *Yersinia*, *Bordetella* or *Brucella*.

38. The method according to claim 37 wherein the bacterium is selected from *Salmonella typhimurium*, *Salmonella typhi*, *Salmonella enteritidis*, *Salmonella choleraesuis*, *Escherichia coli*, *Haemophilus influenzae*, *Neisseria gonorrhoeae*, *Yersinia enterocolitica*, *Bordetella pertussis* or *Brucella abortus*.

Withdrawal of Rejections

E. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The new matter rejection of claims 1,7-17, 20, 25, 27 and 31-41 under 35 U.S.C. 112, first paragraph;
- b) The written description rejection of claims 1,7-17, 20, 25, 27 and 31-41 under 35 U.S.C. 112, first paragraph; and
- c) The rejection of claims 1,7-17, 20, 25, 27 and 31-41 under 35 U.S.C. 103(a) as being unpatentable over Lazer et al., (1996) in view of Dougan et al (US patent 5,527,529).

Allowable Subject Matter

F. Claims 1, 7-9, 11-17, 20, 27, 31-33, and 35-45 are allowed.

G. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
February 12, 2004